

**REMARKS**

***Status of the Claims***

Claims 1-3, 5-10, 22-24, 26-29 and 32-49 are in the application.

Claims 9, 10 and 38-49 have been cancelled without prejudice to their presentation in an divisional application.

Claims 50-73 have been added.

Claims 1-3, 5-8, 22-24, 26-29 and 32-37 are rejected.

Claims 1, 5, 8, 22, 28, 29, 35, and 47 have been amended.

Upon entry of this amendment, claims 1-3, 5-8, 22-24, 26-29 and 32-37, and 50-73 will be pending and subject to examination.

***Summary of the Amendment***

Claims 5, 29, 35, and 47 have been amended to correct typographical and grammatical errors. Claims 1, 8, 22, and 28 have been amended to recite that the nucleic acid molecule comprises encodes a protein comprising an IgE leader sequence and/or at least one IgE epitope and at least one nonIgE epitope that are fused by a proteolytic cleavage sequence. Claims 50-73 have been added and refer, in part, to a nucleic acid molecule comprising a protein encoding an IgE leader sequence and/or a nucleic acid molecule encoding a protein comprising at least one IgE epitope and the nonIgE epitope being fused by a proteolytic cleavage sequence. Support for this amendment can be found in, for example, Example 1 (p. 16-17 of the as-filed specification). Claims 9, 10 and 38-49 have been cancelled without prejudice to their presentation in an divisional application.

No new matter has been added.

***Claim Objections***

Claims 5 and 35 were objected to because of alleged minor informalities. Applicants have amended the claims to remove the extraneous period. In view of the amendments, Applicants respectfully request that the objections be withdrawn.

***Claim Rejection Under 35 U.S.C. § 102***

Claims 1-3, 5-8, 22-24, 26-29, and 32-37 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by WO 02/20038. Applicants respectfully disagree.

WO 02/20038 does not anticipate the amended claims because it does not disclose each and every element of the pending claims. Claims 1 and 22 have been amended to recite that the “epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence.” Claim 8 has been amended to recite that the nucleic acid molecule comprises an IgE leader sequence. For a reference to anticipate a claim it must disclose each and every element as arranged in the pending claims. The WO 02/20038 reference does not disclose a nucleic acid molecule, a vaccine composition, or a host cell with an “epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence.” The WO 02/20038 reference also does not disclose a nucleic acid molecule, a vaccine composition, or a host cell, comprising a nucleic acid molecule that encodes a protein comprising an IgE leader sequence. The reference also does not anticipate new claims 50-73 because the reference fails to disclose an IgE leader sequence and/or an epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence. (See, WO 02/20038, lines 5-19). Accordingly, WO 02/20038 does not disclose each and every element and, therefore, fails to anticipate the pending claims.

Claims 1-3, 5-8, 22-24, 26-29, and 32-37 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Klysner et al (US2002/0172673). Applicants respectfully disagree.

The Klysner reference does not anticipate the amended claims because it does not disclose each and every element of the pending claims. Claims 1 and 22 have been amended to recite that the “epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence.” Claim 8 has been amended, in part, to recite that the nucleic acid molecule encodes a protein comprising an IgE leader sequence. For a reference to anticipate a claim it must disclose each and every element as arranged in the pending claims. The Klysner reference does not disclose a nucleic acid molecule, a vaccine composition, or a

host cell with an “epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence.” The Klysner reference also does not disclose a nucleic acid molecule, a vaccine composition, or a host cell, comprising a nucleic acid molecule that encodes a protein comprising an IgE leader sequence. The reference also does not anticipate new claims 50-73 because the reference fails to disclose an IgE leader sequence and/or an epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence. (Klysner, ¶ 180) Accordingly, The Klysner reference does not disclose each and every element and, therefore, fails to anticipate the pending claims.

Claims 1-3, 22-24 and 28 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Chen et al. (WO 98/53843). Applicants respectfully disagree.

The Chen reference does not anticipate the amended claims because it does not disclose each and every element of the pending claims. Claims 1 and 22 have been amended to recite that the “epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence.” Claim 8 has been amended to recite, in part, that the nucleic acid molecule encodes a protein comprising an IgE leader sequence. For a reference to anticipate a claim it must disclose each and every element as arranged in the pending claims. The Chen reference does not disclose a nucleic acid molecule, a vaccine composition, or a host cell with an “epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence.” The Chen reference also does not disclose a nucleic acid molecule, a vaccine composition, or a host cell, comprising a nucleic acid molecule encoding a protein comprising an IgE leader sequence. The reference also does not anticipate new claims 50-73 because the reference fails to disclose an IgE leader sequence and/or an epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence. Accordingly, the Chen reference does not disclose each and every element and, therefore, fails to anticipate the pending claims.

In view of the foregoing, Applicants respectfully request that all rejections under 35 U.S.C. § 102 be withdrawn.

***Claim Rejection Under 35 U.S.C. § 103***

Claims 5-8, 26, 27, 29, and 32-37 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chen et al. (WO 98/53843) in view of Wang et al. (WO 99/67293) and in view of Hollis et al. (US 5,629,415). Applicants respectfully disagree.

The cited references do not render the claims obvious because the references alone or in combination do not yield the present invention. As discussed above, the amended claims recite that the “epitope of membrane IgE and said nonIgE helper T cell epitope are fused by a proteolytic cleavage sequence” or that the nucleic acid molecule encodes a protein comprising an IgE leader sequence. None of the cited references disclose fusing the epitope of membrane IgE and the nonIgE helper T cell epitope with a proteolytic cleavage sequence. The addition of the cleavage sequence is not obvious because the addition of the cleavage sequence is advantageous. Applicants state that, “to enhance immune response in vivo” the nonIgE helper T cell epitope was fused to the IgE epitope by a proteolytic cleavage site. (Specification, page 17, lines, 14-16). Additionally, the references alone or in combination do not disclose a nucleic acid molecule encoding a protein comprising an IgE leader sequence. The references do not suggest or disclose a nucleic acid molecule, a vaccine composition, or a host cell comprising such compositions and methods as claimed. Therefore, even if the references were combined the combination does not yield the present invention. Accordingly, the pending claims are not obvious because the combination does not produce the claimed invention.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

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***Conclusion***

Claims 1-3, 5-8, 22-24, 26-29 and 32-37, 50-73 are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7820 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

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